

REMARKS

Entry of the above amendments and reconsideration and withdrawal of the rejection of claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132, and 134-147 is respectfully requested. Claims 1, 18, 20, 24, 73, 75, 81, 114, 121, 139, and 142 were amended to correct typographical errors.

I. The Written Description Rejection under 35 U.S.C. § 112, First Paragraph

The Office states that claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Particularly, the Office states that the specification does not provide support for the following limitations: 1) the “first and second dissolution modifying excipient,” 2) “the capsule shell upon being exposed to a gastro-intestinal environment dissolves in a time/controlled release dependent manner; and 3) the limitations of claims 144 and 145. Applicants respectfully traverse.

Applicants submit that the specification does provide support for all three limitations. Regarding the first limitation, the specification discloses the novel blending of excipients to render the polymers suitable for injection molding. (Specification: pg 24, lines 4-6). Regarding the second limitation, support is provided in Examples 1-53, in which capsule shells are exposed to gastro-intestinal fluid, and dissolved in a time/controlled release dependent manner (Specification: pg. 37-49; more specifically pg. 45, lines 3-16). Regarding the third limitation, support is also provided in Examples 1-53 (Specification: pg. 37-49).

Applicants submit that claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request that the Office reconsider and withdraw the 35 U.S.C. § 112, first paragraph, rejection of claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147, as amended.

II. The Enablement Rejection under 35 U.S.C. § 112, First Paragraph

The Office states that Claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132, 134-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office alleges that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. Applicants respectfully traverse the rejection.

Applicants submit that the claims are enabled under 35 U.S.C. § 112, first paragraph. Clarification of such enablement is provided in the analysis of the Wands factors.

The Breadth of the Claims

The claims are set forth herein and above.

The State of the Prior Art and the Predictability or Lack Thereof in the Art

The Office states that the prior art teaches that copolymer of methyl acrylate, methyl methacrylate and methacrylic acid is known to have pH-dependent property. The Office alleges that the present specification does not provide any adequate guidance for the limitation “substantially pH-independent.”

Applicants respectfully submit that one of skill in the art would clearly understand the patent application as providing clear direction how to make the claimed invention. For example, the specification provides a detailed disclosure and teaching about pH-independence of the copolymers:

One aspect of the present invention is the novel blending of components which has the ability to render the poly(meth)acrylates, such as 4135F, which are pH dependent independent of this characteristic. They are no longer governed by the pH of the solution, i.e. the gastric tract, but are time/controlled release dependent instead, which determination is based upon the addition of the swellable solids and surfactants. (Specification: pg. 24, lines 33-36; pg.25, lines 1-2)

Additionally, the Examples describe in detail how to manufacture a variety of multicomponent pharmaceutical dosage forms with the correct blending of components that will render the copolymers to be pH independent. (Specification: pg. 37-49). Example 1 illustrates the “process used to mold the various multicomponent capsules and appropriate subunits.” (Specification: pg. 37-38). Examples 1-53 show that these copolymers are time/controlled release dependent. (Specification: pg. 37-49). The guidance provided in the description in the specification, and in the examples is sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

The Quantity of Experimentation Needed

The Office states that there is a substantial gap between a composition comprising the claimed copolymer, and one comprising the same copolymer but obtain different properties. The Office restates that that the prior art teach that copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid is pH-dependent. The Office alleges that a burdensome amount of research would be required by one of ordinary skill in the art

to bridge this gap.

Applicants respectfully submit that one skilled in the art, in possession of the detailed disclosure of the instant specification would be able to practice the invention without undue experimentation. In fact, 53 examples are provided at pages 37 to 49 to guide the skilled person in the manufacture of pH independent copolymeric dosage forms.

The Level of Skill in the Art

The level of skill in the art is that of a scientist having education and training in capsule technology, and is capable of producing the compound of the invention without the need for undue experimentation.

Based on all of the Wands factors and consideration of the evidence as a whole, it is respectfully submitted that the patent application includes a description of the claimed invention in compliance with §112, such that the rejections of 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 35, upon reconsideration, should be withdrawn.

III. The 35 U.S.C. § 112, Second Paragraph

The Office states that claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132, and 134-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 73 are rejected for alleged use of improper Markush language.

In response, claims 1 and 73 were amended in line 20 of claim 1, and in line 17 of claim 73 to replace the word “or” with the word “and.”

The Office alleges that claims 1 and 73 are rejected because it is not entirely clear whether items (a) through (d) in the claims are supposed to be altogether or in an alternative manner.

In response, claims 1 and 73 were amended to include the word “and” in line 29 of claim 1, and in line 25 of claim 73.

The Office alleges that claim 73 recites the limitation “the capsule shell” in third to last line, and that there is insufficient antecedent basis for this limitation in the claim.

In response, Applicants have amended claim 73 to replace the phrase “capsule shell” in the third to last line with the phrase “outer surface.”

The Office alleges that claims 18, 20, 24, 75, 81, 114, 121, 139, and 142 are rejected in view of the word “and” preceding the word “combinations” or “mixtures thereof.” The Office alleges that it is not entirely clear whether all of the components recited in the

claims are used together as a combination, a mixture, or individual.

In response, Applicants have amended claims 18, 20, 24, 75, 81, 114, 121, 139, and 142 to replace the phrase “and combinations and mixtures” with the phrase “or a combination or a mixture.” Applicants submit that the components recited in claims 18, 20, 24, 75, 81, 114, 121, 139, and 142 can be used as a combination, or a mixture, or individually. Support can be found for claims 18, 75, 139, and 142 on page 26, lines 15-37, and page 27, lines 1-3 of the specification. Support can be found for claim 20 on page 27, lines 11-23. Support can be found for claim 24 on page 27, lines 4-10. Support can be found for claim 81 on page 29, lines 1-20. Support can be found for claims 114 and 121 on page 28, lines 4-18.

The Office states that claim 147 is rejected for failing to further limit the subject matter of claim 73. Particularly, the Office states that claim 73 recites lubricant in an amount of “10 to about 30%,” however, claim 147 recited lubricant in an amount of “about 10.” The Office alleges that the term “about” includes limitations below 10%, which is outside the range recited in claim 73.

In response, claim 73 was amended to include the word “about” in line 8 of claim 73. Support for this amendment can be found in the specification on page 29, lines 8-9.

Applicants submit that claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132, and 134-147 satisfy the requirement of 35 U.S.C. § 112, second paragraph. Applicants respectfully request that the Office reconsider and withdraw the 35 U.S.C. § 112, second paragraph rejection of claims 1-14, 16-33, 35, 38-40, 71-88, 90-97, 112-132 and 134-147, as amended.

CONCLUSION

Applicant respectfully requests reconsideration of the rejection of the above-mentioned claims and request an early and favorable allowance.

Respectfully submitted,

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